

510(k) Summary

K052944

1. 510(k) owner:

Ambu A/S
Baltorpbakken 13
2750 Ballerup
Denmark
Tel.: +45 72252000
Fax.: +45 72252050

OCT 25 2006

Contact person:
Poul Ottosen
Corporate Quality Manager

Preparation date of the 510(k) summary: 10 October 2005

2. Name of device:

Device Common name: Disposable ECG electrode

Device Trade name: Ambu® White Sensor CFM
Ambu® White Sensor CFL

Classification Name: Electrode, Electrocardiograph.
21 CFR 870.2360

Product Code: DRX

3. Identifies the legally marketed device to which equivalence is claimed

<u>Manufacturer</u>	<u>Trade Name</u>	<u>Product code</u>
Ambu A/S	Ambu® Disposable ECG Electrode	DRX
3M	Red Dot 2560	DRX

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4. Description of device

Ambu® White Sensor CFM/CFL are non-sterile, self adhesive, multifunction ECG electrodes. Ambu® White Sensor CFM/CFL should only be used by or on the order of a physician.

Ambu® White Sensor CFM/CFL are single patient use disposable devices.

Ambu® White Sensor CFM/CFL are multi-layer constructions containing a metal stud, a plastic eyelet sensor, hydrogel, foam with medical adhesive and a polymer topfilm.

5. The intended use

Ambu® White Sensor CFM/CFL are for multipurpose ECG monitoring.

6. Summary of the technological Characteristics

The technological characteristics of Ambu® White Sensor CFM/CFL are identical to the predicate devices.

Ambu® White Sensor CFM/CFL are multi-layer constructions containing a metal stud, a plastic eyelet sensor, hydrogel, foam with medical adhesive and a polymer topfilm.

7. Brief discussion of the nonclinical tests submitted

The non-clinical tests performed are laboratory tests to ensure the electrical and mechanical functionality of the electrode meets the standard ANSI/AAMI EC12:2000 – Disposable ECG Electrodes.

8. Brief discussion of the clinical tests submitted

No clinical tests are performed

9. Biocompatibility testing

The biological safety of the Ambu® White Sensor CFM/CFL have been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. Tests were selected on the basis of ISO 10993-1 – Biological evaluation of Medical Devices.

10. Conclusions drawn from the nonclinical, clinical and biocompatibility tests

Aging test of Ambu® White Sensor CFM/CFL and comparison test to predicate devices have been performed. From the results it has been concluded that the Ambu® White Sensor CFM/CFL have equivalent electrical and mechanical functionality as the predicate devices.

The Ambu® White Sensor CFM/CFL meet the mandatory performance standard requirements under ANSI/AAMI EC12:2000 – Disposable ECG electrodes.

The biocompatibility of the Ambu® White Sensor CFM/CFL have been established.

It is concluded that Ambu® White Sensor CFM/CFL are safe and effective electrodes and comparable to the predicate devices.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2006

Ambu Inc.
c/o Mr. Sanjay Parikh
Technical and Regulatory Affairs
6740 Baymeadow Dr.
Glen Burnie, MD 21060

Re: K052944

Trade Name: Ambu® White Sensor CFM & Ambu® White Sensor CFL
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: II (two)
Product Code: DRX
Dated: September 26, 2006
Received: September 29, 2006

Dear Mr. Parikh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman" with a stylized flourish at the end.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052944

Device Name: Ambu® White Sensor

Indications For Use:

Ambu® White Sensor electrode is for multipurpose ECG monitoring. The ECG electrode is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram. The electrode is for single patient use only.

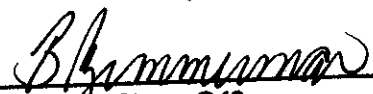
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052944

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